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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/585,645 06/01/00 ZOGHBI

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026271 HM12/0914
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EXAMINER

QIAN, C

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

09/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/585,645	Applicant(s) ZOGHBI ET AL.	
	Examiner Celine Qian	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-119 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-119 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to an animal having an inactivated atonal-associated nucleic acid sequence and a method of screening a compound which affects expression of atonal-associated nucleic acid sequence in said animal.
- II. Claims 20-29 and 112-119, drawn to a method of treating an animal with a deficiency in cerebellar granule neurons and a composition comprising atonal-associated nucleic acid sequence.
- III. Claims 30-39 and 112-119, drawn to a method of promoting mechanoreceptive cell growth in an animal and a composition comprising atonal-associated nucleic acid sequence.
- IV. Claims 40-50 and 112-119, drawn to a method of generating hair cell and a composition comprising atonal-associated nucleic acid sequence.
- V. Claims 51-61 and 112-119, drawn to a method of treating an animal with hearing impairment and a composition comprising atonal-associated nucleic acid sequence.
- VI. Claims 62-72 and 112-119, drawn to a method of treating an animal with imbalance disorder and a composition comprising atonal-associated nucleic acid sequence.

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- VII. Claims 73-84 and 112-119, drawn to a method of treating an animal for a joint disease and a composition comprising atonal-associated nucleic acid sequence.
- VIII. Claims 85-100 and 112-119, drawn to a method of treating an animal with abnormal cell proliferation and a composition comprising atonal-associated nucleic acid sequence.
- IX. Claims 101-111 and 112-119, drawn to a method of treating an animal for a disease resulting from loss of functional atonal-associated nucleic acid or amino acid sequence and a composition comprising atonal-associated nucleic acid sequence.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and different modes of operation. Although the animal having an inactivated atonal-associated nucleic acid sequence of invention of Group I may have cerebellar neuron deficiency, the method of treating said disease of the invention of Group II is not limited to treat such animal only. Furthermore, the animal of the invention of Group I can also be used to screen compounds which affect atonal-associated nucleic acid sequence expression. Thus, the compositions and methods of the invention I and II are patentably distinct.

Inventions I and II, III, IV, V, VI, VII, VIII or IX are patentably distinct because of the same reasons as discussed above.

Inventions II and III are patentably distinct because the inventions are drawn to distinct methods treating different conditions which require different starting material and different mode of operation. The delivery method and therapeutically effective amount of an atonal-associated amino acid sequence to treat cerebellar granule neuronal deficiency of the invention of Group II is not same as promoting mechanoreceptive cell growth in an animal of the invention of Group III. Thus, the methods of the invention of Group II and III are patentably distinct.

Inventions II, III, IV, V, VI, VII, VIII and IX are patentably distinct because of the same reasons as discussed above.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0823. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
September 6, 2001

A handwritten signature in black ink, appearing to read 'Remy Yucel', with a stylized, cursive script.

REMY YUCEL, PH.D
PRIMARY EXAMINER